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IN THE UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
	PLAINTIFFS' RESPONSE TO DEFENDANTS C. R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF DEREK MUEHRCKE, M.D.

Plaintiffs oppose Defendants' Motion to Exclude the Opinions of Derek Muehrcke, M.D. ("Motion" or "Mot.") [Doc. 73044]. Plaintiffs incorporate in this response their Omnibus Statement of Law and Generally-Applicable Arguments in Opposition to Bard's Motions to Exclude Plaintiffs' Experts under Rule 702 and *Daubert* ("Omnibus Mem.") [Doc. 7799], filed contemporaneously herewith. For the reasons set forth herein and in the Omnibus Memorandum, this Court should deny the Motion.

I. INTRODUCTION

Derek Muehrcke, M.D., has been a practicing cardiothoracic surgeon for the past 24 years. Dr. Muehrcke received his medical degree from Rush Presbyterian St. Luke Medical Center, and he received specialty training at Harvard University and Massachusetts General Hospital. Dr. Muehrcke was on staff at the Cleveland Clinic, and he is now Chief of Cardiothoracic Surgery at a hospital near Jacksonville, Florida. Dr.

Muehrcke performs approximately 700 cases per year, including approximately 20 implants and 25 removals of IVC filters each year. Dr. Muehrcke also has published dozens of articles in scientific journals, and has given presentations around the world.

Despite Dr. Muehrcke's impressive qualifications, several of Defendants' attacks on his opinions focus on his alleged lack of qualifications to opine on certain issues. As discussed below, the Ninth Circuit does not employ strict standards when an expert witness's qualifications are challenged. But regardless of the law, Dr. Muehrcke's education, training, knowledge, and experience render him well qualified to give all of the opinions that he is offering—both his general opinions about Bard's products and his case-specific opinions regarding five of the bellwether Plaintiffs.

Dr. Muehrcke also has utilized a reliable methodology in developing his opinions. He testified that he used the same methods in reaching his opinions for litigation as he would in treating a patient or writing an article for a scientific journal, which is all that *Daubert* requires. *See Boyd v. City & County of San Francisco*, 576 F.3d 938, 946 (9th Cir. 2009). But the reality is, Dr. Muehrcke's study was more rigorous in this litigation because he had the opportunity to review Bard's internal documents in forming his opinions. He also reviewed the scientific literature, the pertinent medical records and radiology films, and various depositions. That study, along with the knowledge gained from 21 years of implanting and removing IVC filters, form a solid foundation for all of Dr. Muehrcke's opinions.

As discussed in detail below, all of Bard's attacks on Dr. Muehrcke's opinions raise issues that should be addressed on cross-examination. Dr. Muehrcke is a well-qualified expert who has used reliable methods, so none of his opinions should be excluded under Rule 702.

A. Dr. Muehrcke's Qualifications

Dr. Muehrcke has practiced as a board certified cardiothoracic surgeon for more than 24 years. (*See* Exhibit A to Defendants' Motion at 1, Muehrcke Rule 26 Expert Report for Sherri Booker (hereinafter "Def. Ex. A").) Dr. Muehrcke graduated from a

seven-year undergraduate/medical school program at Grinnell College and Rush Presbyterian St. Luke Medical Center in Chicago. Dr. Muehrcke's specialty training took place at Harvard Medical School and Massachusetts General Hospital, where he completed his surgical residency and training in adult cardiothoracic surgery. (*Id.*) He further served as a resident in vascular surgery in Plymouth, England, and in thoracic surgery in Liverpool, England. (*Id.* at CV p. 2.)

After his fellowship program, Dr. Muehrcke's first staff position was at the Cleveland Clinic, where he performed adult cardiac surgery for three years. (Def. Ex. A at 2.) Dr. Muehrcke then moved to Florida, where he joined four other Harvard-trained cardiovascular surgeons in private practice. (*Id.*) Dr. Muehrcke and his team perform cardiac, thoracic, and vascular surgery at seven hospitals in the Jacksonville area. Dr. Muehrcke is the Chief of Cardiothoracic Surgery at one of those hospitals, Flagler Hospital in Saint Augustine, Florida. (*Id.*)

As part of his work as a surgeon, Dr. Muehrcke has implanted and removed every iteration of Bard's retrievable filters, from the Recovery through the Denali. (*Id.*) He has also implanted IVC filters from various other manufacturers. (*Id.*) Dr. Muehrcke performs approximately 700 surgical cases per year. He estimates that he implants approximately twenty IVC filters each year and removes approximately twenty-five IVC filters each year. (*Id.*) Dr. Muehrcke is licensed to practice medicine in Ohio, Florida, and Georgia. (*Id.* at CV Page 5.)

Dr. Muehrcke is a member of the Society of Thoracic Surgeons and a fellow in the American College of Surgeons. (Def. Ex. F at 14:5-8, Deposition of Derek Muehrcke.) He regularly attends presentations and conferences for the Society of Thoracic Surgeons. (*Id.* at 14:9-12.) Dr. Muehrcke has also given presentations in several countries; he has authored or co-authored forty-three published articles in scientific journals; and he has authored or co-authored four textbook chapters. (Def. Ex. A at CV Pages 6-10.)

B. Dr. Muehrcke's Methodology in Forming His Opinions

The Plaintiffs retained Dr. Muehrcke to give opinions in five bellwether cases, those involving injuries suffered by Sherri Booker, Lisa Hyde, Doris Jones, Carol Kruse, and Debra Mulkey. (*See generally* Def. Exs. A-E, Dr. Muehrcke's Rule 26 expert report as to each Plaintiff.) In forming his opinions regarding Bard's IVC filters and their impacts on these five women, Dr. Muehrcke has relied on all of the following sources:

- His personal, professional experiences with IVC filters;
- His background, education, and training;
- His review of the scientific literature regarding IVC filters;
- His review of each patient's medical records and radiology reports;
- His knowledge of recognized and accepted principles of medicine;
- His review of Bard's internal documents; and
- His review of depositions taken in the Bard IVC filter litigation.

(Def. Exs. A-E at Page 1 of each report.)

During his deposition, Dr. Muehrcke was asked whether he had exercised "the same level of intellectual rigor that you exercise in the practice of medicine" when forming his opinions for this case. He responded: "Yes. So the methodology for my causation and my liability opinions are based on the same care and skill I would use to address a patient to write a peer review article in the field of medicine." (Def. Ex. F at 163:12-20.) Dr. Muehrcke was also asked to explain his methodology in reviewing the medical literature in other documents. He responded:

> A. I did … a general review of the literature[,] on the BARD literature, inferior vena cava literature, expanded out to different types of … filters. And having been able to pull the curtain back on the BARD documents I was able to see the very concerning results of their own internal studies, not only migration testing, but also complications of the early filters, and corroborated that with the literature, the medical literature.

(*Id.* at 164:3-17.) Dr. Muehrcke further explained that he engaged in a systematic and independent review of the medical literature, which helped him to arrive at his opinions. (*Id.* at 177:23-178:14.)

In forming opinions as to the individual Plaintiffs, Dr. Muehrcke reviewed the medical records and radiology records for all five of them. (Def. Exs. A-E at 6-7 of each report; *see also* Def. Ex. F at 49:11-16 (stating that he had reviewed "all the imaging which is in the report" and "all of the medical records").) All of the opinions expressed in his reports were reached to a reasonable degree of medical certainty. (Def. Ex. F at 163:1-4.)

Dr. Muehrcke also reviewed a large number of Bard's internal documents, as described in all of his reports and discussed at his deposition. (Def. Ex. B at 4-6; Def. Ex. F at 187:5-17.) Based on his review, Dr. Muehrcke has stopped using any of Bard's IVC filters in his own practice, because he has "lost my trust" in the BARD line of IVC filters. (Def. Ex. F at 26:25-27:25.)

II. DAUBERT STANDARD

The standard for admission of expert testimony under Rule 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), is explained in greater detail in Plaintiffs' Omnibus response brief, which is hereby incorporated by reference. But a few key points are reiterated here. In addition, further exposition of the legal standard appears in the Argument section, as relevant to particular issues.

The first question under the rule is whether the expert is qualified "by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. As another judge of this Court has written, "Rule 702 'contemplates a broad conception of expert qualifications... [and] is broadly phrased and intended to embrace more than a narrow definition of qualified expert.'" *Ericson v. City of Phoenix*, No. CV-14-01942-PHX-JAT, 2016 WL 6522805, at *3 (D. Ariz. Nov. 3, 2016) (quoting *Thomas v. Newton Int'l Enters.*, 42 F.3d 1266, 1269 (9th Cir. 1994)). Therefore, "it is an abuse of discretion to exclude testimony simply because the trial court does not deem the proposed expert to be the best qualified

or because the proposed expert does not have the specialization that the court considers most appropriate." *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008).

The remainder of the inquiry focuses on two issues: (1) whether the opinion reflects scientific knowledge, and (2) whether it will assist the jury. *Kennedy v. Collagen Corp.*, 161 F.3d 1226, 1228 (9th Cir. 1998). "The 'will assist' requirement, under *Daubert*, goes primarily to relevance." *Primiano*, 598 F.3d at 567 (quotations omitted). Expert testimony "is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry." *Id.* at 565.

Generally speaking, the purpose of the *Daubert* inquiry is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Boyd*, 576 F.3d at 946 (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999)). The *Daubert* Court also cautioned that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

III. ARGUMENT

The Court should reject all of the Defendants' challenges to Dr. Muehrcke's qualifications and methodology. The issues are addressed below in the order raised by the Defendants' motion.

A. Dr. Muehrcke Is Well Qualified to Opine, from a Clinical Perspective, As to How the Design of Bard's Filters Led to Numerous Complications That He Has Observed in Writings and in His Own Practice.

Despite Dr. Muehrcke's impressive academic credentials, his distinguished career as a cardiothoracic surgeon, and his extensive experience with implanting and explanting Bard's IVC filters, several of Defendants' arguments attack his qualifications to testify. The Defendants' first argue that Dr. Muehrcke should be precluded from offering any opinions about the design of Bard's filters. Bard asserts that Dr. Muehrcke is a medical

doctor, not an engineer. (Motion at 3.) But Dr. Muehrcke's experience with IVC filters, along with his general medical knowledge and his review of literature and Bard documents, render him well qualified by knowledge and experience to opine, from a clinical perspective, as to the performance flaws caused by Bard's filter designs.

Notably, Bard relies almost entirely on opinions from outside of the Ninth Circuit in support of its argument. (*See* Motion at 4.) In discussing the Ninth Circuit standard for qualifications, the court wrote that Federal Rule of Evidence 702 "contemplates a broad conception of expert qualifications." *Thomas*, 42 F.3d at 1269. The rule requires only a "minimal foundation" to be qualified to give expert testimony. *Id.* at 1269-70; *see also Hangarter v. Provident Life & Acc. Ins. Co.*, 373 F.3d 998, 1016 (9th Cir. 2004). Further, "the advisory committee notes emphasize that Rule 702 is broadly phrased and intended to embrace more than a narrow definition of qualified expert." *Thomas*, 42 F.3d at 1269. "Any one or more of the bases given" in Rule 702 "is sufficient to qualify a witness as an expert." *Heighley v. J.C. Penney Life Ins. Co.*, 257 F. Supp. 2d 1241, 1254 (C.D. Cal. 2003) (citing 4 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence*, § 702.04 [1][c] (Joseph M. McLaughlin, ed., Matthew Bender 2d ed. 2002)).

In *Ericson*, this Court assessed the credentials of a nurse practitioner to opine about the effects of an officer's carotid hold on the decedent's death. *Ericson*, 2016 WL 6522805, at *4. The defendant argued that she was unqualified to offer that opinion because she was "not an emergency room doctor, forensic medical examiner, forensic pathologist, toxicologist, biomechanical or human factors expert, or police officer." *Id.* But the Court allowed the opinion, stating that the nurse's "knowledge and experience related to strangulation and its effects are extensive." *Id.*

Here, Dr. Muehrcke also has extensive knowledge and experience as it relates to the design of Bard's filters. He is not offering any opinions about an alternative design. (Def. Ex. F at 90:4-6.) Rather, he opines that the Bard filter designs are inadequate based on the rates of caudal migration. (Def. Exs. A, B, C, and E at p. 7 of each.) He further opines that four of the Plaintiffs' filters tilted, became embedded in their vena cavas, and

suffered from strut fractures. (Def. Ex. A at 9; Def. Exs. B, D, and E at 8.) This result, Dr. Muehrcke opines, was due to "weak anchoring hooks and lack of radial force and inadequate leg span to accommodate vessel distention … ." (*Id.*) Dr. Muehrcke's opinions are informed by his knowledge, his experience, and his study of the literature and Bard's documents:

> Q. What qualifications do you have that entitle you – or that enable you to give opinions on the adequacy of the design of an IVC filter?
>
> A. I'm a physician who actively puts in inferior vena cava filters of all designs, and have to interact with patients and determine which is the most appropriate filter for patients to receive. I do put a lot of filters in and try to take a lot of filters out.
>
> It is – I am the person who is the – where rubber meets the road I am the person who has to interact and take patient safety into account and am responsible for that.

(Def. Ex. F at 88:8-19.) Dr. Muehrcke has also studied the design of Bard's filters and the effect on patients. He specifically noted that the deposition of Bard's Robert Carr was helpful in explaining the design aspects of the various filters. (*Id.* at 53:53:11-25.) Dr. Muehrcke also explained, in detail, how Bard's documents show that the tilt of the filter affects its clot trapping efficiency. (*Id.* at 91:12-92:16.)

As another MDL judge has held, a physician who has ample experience with a particular medical device does not need to be an engineer to opine about product design. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4500765, at *5-6 (S.D. W. Va. Aug. 26, 2016) (permitting urogynecologist's opinions about design of pelvic mesh devices based on his experience, his literature review, and his review of corporate documents). This Court should reach the same conclusion, based on Dr. Muehrcke's extensive experience with IVC filters, his study of the literature, and his study of Bard's internal documents, as described above.

B. Relying on Other Experts Is Proper, and Dr. Muehrcke's Opinions Are Based on Far More Than The Reports of Other Experts; Thus, It Is Absurd To Seek Exclusion of All of His Opinions Simply Because He Reviewed a Handful of Expert Reports.

Bard's next attack is one leveled at a large number of the Plaintiffs' experts, and it is therefore addressed in Plaintiffs' Omnibus Memorandum (Section B). That section is hereby incorporated by reference. However, this brief will also address Bard's argument as it relates to Dr. Muehrcke. Bard is greatly overreaching when it argues that Dr. Muehrcke's general reliance on the reports of other experts somehow contaminates his entire opinions, such that they should all be stricken.

A case relied upon by Bard helps to explain why this argument is meritless. In *In re Toyota Motor Corp. Unintended Acceleration Marketing, Sales Practices, & Product Liability Litigation*, 978 F. Supp. 2d 1053 (C.D. Cal. 2013), the court allowed the testimony of an expert who had relied on three other experts, one witness, and additional data. *See id.* at 1071-72. The same analysis applies here, as Dr. Muehrcke has not relied solely on the opinion of any other expert to reach any of his own opinions.

The bullet-point list above describes seven different sources—in general terms—that Dr. Muehrcke primarily consulted in forming his opinions for this case, and none of them references other experts. Dr. Muehrcke simply states, in his reports, that he "read the expert report of Drs. Kinney, Roberts, and Kalva, and I adopt and agree with the opinions set forth therein. The same is true for the expert report of Mark Eisenberg, M.D." (*See, e.g.*, Def. Ex. B at 6.) As discussed above, Dr. Muehrcke also reviewed scientific literature, Bard documents, numerous depositions, and the patients' medical records and radiological films. (*See, e.g.*, *id.* at 4-6.) None of Dr. Muehrcke's opinions rely solely, or even primarily, on the reports of other experts. Thus, the Defendants are trying to strike otherwise reliable opinions based solely on the fact that Dr. Muehrcke read the reports of other experts. This would be an entirely illogical result.

In addition, as discussed in the Omnibus response brief, there is nothing problematic about experts relying on one another in complex litigation. *See Toyota*, 978 F. Supp. 2d

at 1066. Defendants cherry-pick testimony in asserting that Dr. Muehrcke did not review all of the materials relied upon by those other experts. (*See* Def. Motion at 6.) Of course, that would be an unrealistic expectation in a case such as this one. Nothing in Toyota requires one expert to review **all** of another expert's materials to rely, in part, on the other expert. *See generally Toyota*, 978 F. Supp. 2d 1053. But Dr. Muehrcke did not simply rely on other reports with no further thought. For instance, Dr. Muehrcke testified that he asked for certain documents cited in Dr. Kinney's reports—the fracture analysis—and also testified that he already had many of the other documents cited in that report. (Def. Ex. F at 43:9-18.)

Because Dr. Muehrcke has reached his own conclusions based on all of the evidence, this Court should not exclude his opinions.[1]

C. Dr. Muehrcke Is Offering an Opinion about the Adequacy of Bard's Warnings, Not Speaking on Behalf of Other Physicians, When He Opines That Bard Has Failed to Provide Information That Physicians Need to Know to Offer Truly Informed Consent to Patients.

Bard's third attack is also an argument that Bard has raised against many of the Plaintiffs' experts, claiming that Dr. Muehrcke is improperly speaking on behalf of other physicians. But he is doing no such thing. Again, this issue is addressed in the Omnibus response (Section A), which is incorporated by reference herein.

In opining that Bard failed to tell physicians information that they needed to know, Dr. Muehrcke is opining that Bard failed to give physicians the information they need to engage in a proper informed consent process with their patients—including the five Plaintiffs on whose cases Dr. Muehrcke is opining. In giving the opinion that the Bard

[1] While the Court should conclude that all of Dr. Muehrcke's opinions are admissible, it is worth noting that he relied on other experts only for general information about Bard's filters. He reviewed every individual Plaintiff's medical records and radiological films **personally**. (Def. Ex. F at 49:11-16.) Thus, there is absolutely no basis to conclude that Dr. Muehrcke's reliance on other experts has somehow infected his specific causation opinions. Yet, Bard seeks to exclude Dr. Muehrcke's opinions entirely—apparently including even his specific causation opinions—simply because he relied in some small part on other experts' reports.

G2 filter "did not perform in a manner reasonably expected by physicians and patients, nor in the manner represented by Bard," (*see, e.g.*, Def. Ex. B at 8), Dr. Muehrcke is clearly opining that the warnings and other information provided by Bard to physicians was insufficient.

Dr. Muehrcke's opinion—which expressly mentions "the manner represented by Bard"—is an opinion that Bard did not provide physicians with adequate information about the risks presented by its IVC filters. As he testified during his deposition, "doctors need to know more about the complication rates, which BARD had access to that information only." (Def. Ex. F at 85:8-15.) Dr. Muehrcke further explained that "BARD had a lot of internal data which showed a problem with the filter, never elected to do a study to find out if those were valid responses, and that information should have been given to doctors." (*Id.* at 84:16-20.)

Dr. Muehrcke knows the type of information that physicians need to know because he has been a practicing cardiothoracic surgeon for 24 years, and he regularly implants and explants IVC filters. (*See* Def. Ex. A at 1-2.) Bard complains that Dr. Muehrcke has not formally surveyed physicians to determine what they want to know, but a survey would be unnecessary. Physicians need to have the necessary information to give their patients truly informed consent about medical procedures, and it is universally accepted that risk information needs to be a part of that informed consent process.

For instance, guidelines written by the American College of Radiology and two related societies address informed consent procedures. (*See* ACR-SIR-SPR Practice Parameter on Informed Consent for Image Guided Procedures (2016), available at htts://www.acr.org/~/media/1A03224CA4894854800C516012B6DB5A.pdf, attached as Exhibit 1.) The guidelines list six necessary aspects of any informed consent. The third item listed is "[t]he risks, complications, and expected benefits or effects of such procedure or treatment." (*Id.* at p. 3.) One of Bard's expert witnesses, Donna-Bea Tillman, Ph.D, testified that "physicians need to have enough information to understand the risks and the benefits in order to advise their patients." (Deposition of Donna-Bea

Tillman, attached as Exhibit 2, at 292:1-10.) As stated in an article in the New England Journal of Medicine, "physicians must know about the performance features of any device they recommend for a patient, so that they can carry out their ethical obligation of obtaining informed consent." (Robert J. Myerburg, et al., *Life-Threatening Malfunction of Implantable Cardiac Devices*, 354 N. ENG. J. MED. 2309, 2309 (2006) (attached as Exhibit 3).)

The claim that Dr. Muehrcke has no support for his opinions is also baseless. As discussed above, he has reviewed literature, Bard documents, depositions, radiology reports, and medical records. He also has personal experience with Bard's filters. (*See, e.g.*, Def. Ex. A at p. 2.) From his experience and his literature review, Dr. Muehrcke has determined that Bard did not provide physicians with the necessary safety information. While the IFUs indicate that there are potential complications associated with all filters, Dr. Muehrcke opines that there needed to be information about complication rates associated with Bard specifically. (Def. Ex. F at 85:3-15.) As discussed in more detail in Section D, there is substantial evidence that Bard's filters had greater complication rates than other filters. (*See, e.g.*, Steven E. Deso, et al., *Evidence Based Evaluation of Inferior Vena Cava Filter Complications Based on Filter Type*, 33 SEMINARS IN INTERVENTIONAL RADIOLOGY 93, 96 (2016), attached as Exhibit 4,)

Dr. Muehrcke is a physician who implants and explants IVC filters. He has observed their complications, and also has studied them in great depth. It is difficult to imagine someone being more qualified, or having a more reliable foundation, in opining that Bard understated the risks posed by its filters. The mere fact that Bard warned of certain potential complications does not mean that the warnings were adequate. *See Cisson v. C.R. Bard, Inc.*, No. 2:11-CV-00195, 2013 WL 5700513, at *7 (S.D. W. Va. Oct. 18, 2013), *aff'd sub nom. In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913 (4th Cir. 2016) (holding that where Bard warned of complications but not of rates or severity, it was a jury question as to whether the warnings were adequate). Thus, Dr. Muehrcke's warnings opinions are reliable.

D. Dr. Muehrcke Is Well Qualified To Opine About the Caudal Migration Rates of Bard Filters, and His Opinions Are Well Supported by The Scientific Literature, Bard's Internal Documents, And His Own Clinical Experience As a Cardiothoracic Surgeon.

Dr. Muehrcke also opines that the rate of caudal migration caused by Bard's filters is "unacceptable." This description is taken straight from Bard's own documents, yet Bard casts it as an unsupported opinion. Bard also claims that Dr. Muehrcke is unqualified to opine about complication rates. The court should reject all of Bard's arguments regarding caudal migration.

1. Dr. Muehrcke's study of Bard documents and the scientific literature, along with his clinical experience, make him well qualified to opine about migration rates.

Bard's only argument as to qualifications is that Dr. Muehrcke is not an epidemiologist. (See Def. Motion at 8-9.) Bard's cited cases do not indicate that a physician has to be an epidemiologist to provide an opinion on medical causation. *See Morritt v. Stryker Corp.*, 973 F. Supp. 2d 177, 188 (E.D.N.Y. 2013) (allowing treating physician's causation testimony but stating that plaintiffs had offered "no explanation" as to how physician was qualified to opine about manufacturing defects); *In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1243-44 (D. Colo. 1998) (excluding chemist from giving medical opinions where chemist had been excluded by many other courts and was labeled a "troubling witness"). Conversely, when an MDL judge addressed this exact issue with an otherwise well-qualified hematologist, the court wrote: "I need not address again defendant's refrain that epidemiological evidence is required for an opinion to have a reliable basis." *In re Heparin Prod. Liab. Litig.*, 803 F. Supp. 2d 712, 745 (N.D. Ohio 2011), *aff'd sub nom. Rodrigues v. Baxter Healthcare Corp.*, 567 Fed. App'x 359 (6th Cir. 2014).

If Dr. Muehrcke were an epidemiologist and not a physician, Bard would likely argue that he was unqualified to opine about migration rates because he lacked the necessary medical understanding. The reality is, he is qualified by knowledge, training, and experience, based on his clinical experience as well as his literature review and

review of Bard documents. (*See, e.g.*, Def. Ex. A at 1-2.) Dr. Muehrcke clearly exceeds the "minimal foundation" needed to be qualified to opine on migration rates. *See Thomas*, 42 F.3d at 1269-70.

2. Dr. Muehrcke employed the same methods that he uses in his clinical practice and his scientific writings, and he extensively studied Bard documents and the scientific literature.

As to methodology, it is difficult to understand what else Dr. Muehrcke should have done in forming his opinions about migration rates. He has studied the literature; he has studied Bard's internal documents; he has reviewed the medical records and radiological films for all of the Plaintiffs on whose cases he is opining; and he has applied his knowledge gained from implanting and removing dozens of IVC filters each year. (*See* e.g. Def. Ex. A at 1-2.) In addition, Dr. Muehrcke gained helpful knowledge by doing follow-up with patients who had been implanted with Bard filters, after his review of literature and Bard documents caused him to recognize the danger that they posed. (Def. Ex. F at 24:19-25:17.)

In describing his methodology generally, Dr. Muehrcke testified that he employed "the same care and skill I would use to address a patient or to write a peer review article in the field of medicine." (Def. Ex. F at 163:12-20.) This point goes to the heart of the *Daubert* inquiry. *See Boyd*, 576 F.3d at 946 (noting that the purpose of Rule 702 and *Daubert* is to "make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

Dr. Muehrcke's comment is not merely a sound bite, as evidenced by the documents and literature that he discussed at his deposition. For instance, while Bard's motion attacks his conclusion that the migration rates of Bard's IVC filters is "unacceptable," that term comes directly from Bard's internal documents. Dr. Muehrcke testified that he relied in part on the deposition of Bard employee Natalie Wong, and certain documents discussed therein. (Def. Ex. F at 40:17-22, 44:11-45:18, 58:2-13, 61:18-24, 92:13-16,

99:14-100:3.) On March 2, 2006, Ms. Wong circulated an internal DFMEA[2] analysis regarding Bard's IVC filters. (*See generally* Wong Dep. Ex. 543 (Wong e-mail and attachment of March 2, 2006), attached as Exhibit 5.) The analysis concluded that there was an "[u]nacceptable risk per FMEA, type III above threshold." (Deposition of Natalie Wong, attached as Exhibit 6, at 154:8-18; *see also* Ex. 5 at p. 20 (labeled "G2 Caudal Threshold").) The "G2 Caudal Summary" showed 13 complaints from November 7, 2015 to February 28, 2006, a rate of 0.15%. (Ex. 5 at p. 5.) The G2 was compared with two other filters, which had caudal migration rates of 0.01% or 0.00%. (*Id.*) Thus, caudal migrations were a greater problem with the G2 filter. (Ex. 6 at 146:8-17.) Caudal migrations are a serious issue because they can lead to tilt or perforation. (*Id.* at 150:15-24.) Caudal migrations can also result in injuries to patients, to the loss of protection from pulmonary embolisms, and, potentially, to death. (*Id.* at 151:25-152:23; *see also* Ex. 5 at p. 16.)

Dr. Muehrcke also discussed a "G2 and G2X Fracture Analysis" conducted by Bard, dated November 30, 2008. (*See generally* Wong Dep. Ex. 546, attached as Exhibit 7.) For the date range of July 1, 2005 through November 30, 2008, the study identified 56 "commercial complaints," with 32 of those occurring in 2008. (*Id.* at p. 2.) That study also identifies caudal migration rates with the G2 as being significantly greater than with the RNF (Recovery) filter—14% to 3%. (*Id.* at 18; *see also* Ex. 6 at 184:10-185:9.) Dr. Muehrcke relied in part on this analysis in forming his opinions. (*See* Def. Ex. F at 76:13-24, 77:5-12, 100:1-3.)

During Dr. Muehrcke's deposition, he discussed several other documents and studies on which he relied in forming his opinions about the dangers associated with Bard's IVC filters. For instance, he discussed the Angel study, which found a much higher migration rate for the G2 filter, as compared with other filters. (Def. Ex. F at 80:9-24.) He discussed the Nazzal study, which found a higher migration rate with

[2] "DFMEA" is an acronym for Design Failure Mode Effects Analysis.

Bard's Recovery filter, as compared with three non-Bard filters. (*Id.* at 80:25-81:7.) Dr. Muehrcke also discussed the recent Deso study. (*See id.* at 72:25-73:16, 86:13-21, 87:22-88:2.) The Deso study, conducted at Stanford and published in 2016, concluded that "[e]arly conical Bard Peripheral Vascular filters were associated with the highest reported rates of fracture." Deso, 33 SEMINARS IN INTERVENTIONAL RADIOLOGY at 96. The Bard Recovery and G2/G2X/Eclipse filters were among the conical filters with the highest rates of tilting more than 15 degrees during insertion. *Id.* Bard's filters also were among the highest rates of IVC perforation. *Id.* And, Bard's Recovery and G2 filters were two of five with migration rates equal to or greater than 10%. *Id.* Clearly, there is ample support in Bard's documents and the scientific literature for Dr. Muehrcke's opinions, which are also supported by his clinical experience. (*See* Def. Ex. F at 25:22-26:11 (explaining that he has had "a lot of complications" with Bard's filters).)

Bard argues that Dr. Muehrcke's opinions are not reliable because he has not attempted to identify a precise complication rate. That issue is one to be raised on cross-examination, rather than a basis for exclusion. A lack of certainty should not be confused with a lack of reliability. *See In re Trasylol Prod. Liab. Litig.*, No. 08-MD-01928, 2010 WL 1489730, at *8 (S.D. Fla. Mar. 19, 2010) (stating that the fact that an expert witness "does not use absolute terms but rather couches the opinion in terms of 'can' and 'may' does not render it speculative or unreliable"); *In re Heparin*, 803 F. Supp. 2d at 754 (same)). Dr. Muehrcke's opinion is that the complication rate should be "[a]s close to zero as possible over time." (Def. Ex. F at 65:2-5.) This opinion is entirely consistent with the medical literature. For instance, an article in the New England Journal of Medicine—discussing implantable cardiac devices—states that "manufactured products can never be entirely free of flaws, but when the consequence of a malfunction is a potentially fatal event, tolerance and surveillance strategies should aim to achieve a risk of malfunction that is **as close to zero as possible**." Myerburg, 354 N. ENG. J. MED. at 2309 (emphasis added). Dr. Muehrcke's opinion is not unreliable simply because he is

asking Bard to strive for this same goal, rather than picking an arbitrary number that would serve as an "acceptable" migration rate.

Finally, Bard argues that Dr. Muehrcke's opinions as to the Eclipse filter should be excluded because Dr. Muehrcke's analysis does not separate Eclipse from the G2 filters. (*See* Motion at 11.) Bard tries to couch this opinion as a design opinion, trading on its prior assertion that Dr. Muehrcke is unqualified to give design opinions. But Dr. Muehrcke is not giving a "design" opinion simply because he considered the Eclipse in conjunction with the G2 filters. The Stanford Deso study also grouped the G2, G2X, and Eclipse filters into one category, presumably because of their similar designs. *See* Deso, 33 SEMINARS IN INTERVENTIONAL RADIOLOGY at 96 (evaluating the G2, G2X, and Eclipse filters together, but separately from the Bard Recovery filter, in several categories). Again, this issue is best raised on cross-examination. *See Daubert*, 509 U.S. at 596. Moreover, it is undisputed among all of the witnesses deposed in this litigation, including the Bard witnesses, that no design changes were made to the Eclipse from the G2 that addressed caudal migration.

For all of these reasons, the Court should permit Dr. Muehrcke's reliable opinions about the migration rates of Bard filters.

E. Defendants' Argument about Corporate Intent Opinions Greatly Mischaracterizes the Cited Opinions Given by Dr. Muehrcke.

Bard's fifth argument is also addressed in the Omnibus response brief (Section C), which is hereby incorporated by reference. However, it is worth noting that none of the underlined opinions cited by Bard reflect an opinion about Bard's motives, intent, or state of mind. (*See* Def. Motion at 12.) Rather, Dr. Muehrcke is addressing the degree of Bard's knowledge, which is relevant to a failure-to-warn claim. *See, e.g., Kildow v. Breg, Inc.*, 796 F. Supp. 2d 1295, 1299 (D. Or. 2011) (stating that a manufacturer's duty to warn with regard to a medical device "is limited to the dangers of which it knew or reasonably should have known").

Because Bard's knowledge of certain dangers is relevant to the various Plaintiffs' failure-to-warn claims, Dr. Muehrcke's statements about Bard's knowledge are necessary and should not be excluded. He is not going to opine that Bard acted with evil intent or motives.

F. It Is Not Speculation for Dr. Muehrcke to Opine about the Future Prognosis for Ms. Hyde; His Opinion Is Based on His Experience and Medical Judgment, Applying the Evidence from Her Records.

This Court should also reject Bard's final argument, which is relevant only to the case brought by Lisa Hyde. On May 16, 2014, an incidental CT scan showed a fractured IVC filter strut with a filter fragment lodged in the right ventricle of Ms. Hyde's heart. (Def. Ex. B at 7.) A cardiologist recommended that Ms. Hyde limit her exercise until she could have the fragment removed. At that time she had an occasional "fluttering" sensation in her chest. (*Id.*) The filter fragment has been removed, but Ms. Hyde still must refrain from activities that raise her heart rate. (*Id.*)

In addition to his opinions about the injuries that Ms. Hyde has already suffered—which are not challenged—Dr. Muehrcke opines that "as a result of the failure of Ms. Hyde's G2 filter and resulting need for additional surgery involving the heart, she is at risk for arrhythmias, need for AICD [automatic implantable cardioverter-defibrillator], and sudden death." (*Id.* at 7-8.) Bard seeks to exclude this opinion, asserting that Dr. Muehrcke is unqualified to give it.

As discussed above, the standard for qualifications is not high. *See Thomas*, 42 F.3d at 1269 (stating that Rule 702 "is broadly phrased and intended to embrace more than a narrow definition of qualified expert"). Dr. Muehrcke is a Harvard-trained cardiothoracic surgeon who has performed surgery at such prestigious hospitals as Massachusetts General Hospital and the Cleveland Clinic. (*See* Def. Ex. B at p. 1.) He has been a board-certified cardiothoracic surgeon for 24 years. (*Id.*) Thus, it is difficult to understand how he could be unqualified to opine about the likely effects of an injury to the heart. His professional life has been spent performing surgery on the heart.

And even if this Court somehow concludes that heart arrhythmias represent a different branch of medicine from cardiothoracic surgery, that (erroneous) conclusion would not render Dr. Muehrcke unqualified to opine about heart arrhythmias. Courts assessing the admissibility of physicians' diagnostic testimony have consistently held that whether physicians "are 'licensed' or have a 'specialty degree' in a particular area generally goes to the weight of their testimony rather than its admissibility." *Chandler v. Guttierrez*, No. EDCV1401169JGBKES, 2017 WL 3224468, at *4 (C.D. Cal. June 14, 2017), *report and recommendation adopted*, No. EDCV1401169JGBKES, 2017 WL 3224684 (C.D. Cal. July 21, 2017) (citing *United States v. Bilson*, 648 F.2d 1238 (9th Cir. 1981) and other cases). There is simply no reasonable basis to conclude that Dr. Muehrcke is unqualified to opine about Ms. Hyde's potential for heart arrhythmias, and about their potential impacts should they occur.

Bard does not challenge the reliability of Dr. Muehrcke's opinion. Bard's only other argument is that the opinion should be excluded because it—supposedly—is not held to a reasonable degree of medical certainty. (Motion at 14.) Dr. Muehrcke made it clear in his report that all of his opinions were held to a reasonable degree of medical certainty. (Def. Ex. B at 8.) He reiterated that point during his deposition. (Def. Ex. F at 163:1-4.) Bard argues, however, that because Dr. Muehrcke did not assign a precise likelihood to Ms. Hyde's potential complications, his opinion could not be held to a reasonable degree of certainty. (Motion at 14.) This argument ignores the obvious point that Dr. Muehrcke is opining that there is a **risk** of future complications. He can be reasonably certain that there is a risk without being able to quantify the risk as a numerical value. Certainly, Bard is free to cross-examine Dr. Muehrcke about his lack of a precise risk value.

During his deposition, Dr. Muehrcke noted that the scarring in Ms. Hyde's heart following the procedure to remove the filter fragment creates a risk of arrhythmias. (Def. Ex. F at 127:2-21.) Both AICD and sudden death would be further complications resulting from serious arrhythmias. (*Id.* at 128:18-22, 129:7-9.) Plus, the fact that Ms.

Hyde's filter malfunctioned leaves her at greater risk of life-threatening pulmonary embolisms. (*Id.* at 132:2-14.) All of these facts support Dr. Muehrcke's opinion.

The Court, therefore, should allow Dr. Muehrcke's opinion about Ms. Hyde's risk of future complications.

IV. CONCLUSION

For all of the foregoing reasons, as well as those stated in Plaintiffs' Omnibus *Daubert* response brief, this Court should deny in its entirety the Defendants' Motion to Exclude the Opinions of Derek D. Muehrcke, M.D.

RESPECTFULLY SUBMITTED this 27th day of September 2017.

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of September, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti